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SUBJECT: HEALTH MINISTRY ADDRESSES US PHARMACEUTICAL
CONCERNS

REF: GRIMM-MANSOUR EMAIL OF 9/27/06

11. (U) In response to U.S. pharmaceutical company and PHRMA concerns (ref), Econoff met with Dr. Batool Jaffer Suleiman, Director of Rational Drug Use, Ministry of Health, on November 7 to discuss Ministerial circular 5/2006, which mandated the re-registration of pharmaceutical companies and their products in Oman. Suleiman noted that the re-registration process would enable the Ministry to keep its records current on the 4,000 products currently on the market in Oman. She also remarked that this routine procedure, to occur every five years, would help the Ministry to update its information on personnel changes and good manufacturing processes.

12. (SBU) Econoff also raised ref concerns regarding the presence of copycat pharmaceutical products in Oman. Suleiman stated that, due to budgetary reasons, the government routed 70% of its pharmaceutical purchases through a centralized GCC-wide tender. As such, she commented that the government depended on the GCC patent office in Riyadh to keep current on potential patent infringements. She expressed concern that the GCC office was not well-equipped to handle patent protection issues, but noted that the government made the decision to rely on the GCC office rather than establishing its own patent office.

13. (SBU) Suleiman also pointed out her concern that U.S. pharmaceutical companies did not have their products registered with the GCC office. As a result, the GCC purchased copycat knockoffs for Combivir (GSK), Fosamax (MSD), and Cozaar (MSD), though these pharmaceuticals were not available for private purchase. On the local front, Suleiman highlighted the fact that the Minister of Health stopped Oman-based National Pharmaceutical Industries (NPI) from producing a copy of Fosamax, and that a copy of Lipator produced by Indian-based Ranbaxy did not receive marketing approval from the Ministry. NPI did receive permission from the government, however, to produce a copycat of Pfizer's Viagra after noting that Viagra was not registered with the GCC patent office.

14. (SBU) Suleiman commented that once the U.S.-Oman Free Trade Agreement (FTA) comes into effect, the Ministry will recognize all U.S. pharmaceutical product patent expiration dates. In this regard, she remarked that the Ministry will ask U.S. pharmaceutical companies, through their representatives in Oman, to submit a master list of the products they produce, to include trade name, chemical name, first filing date, strength, patent expiration date, and a copy of the original U.S. patent. Suleiman also noted that she and her colleagues would be happy to meet with U.S.

pharmaceutical producers on the margins of the December 6
U.S.-Oman FTA awareness conference to discuss the issue
further.

GRAPPO